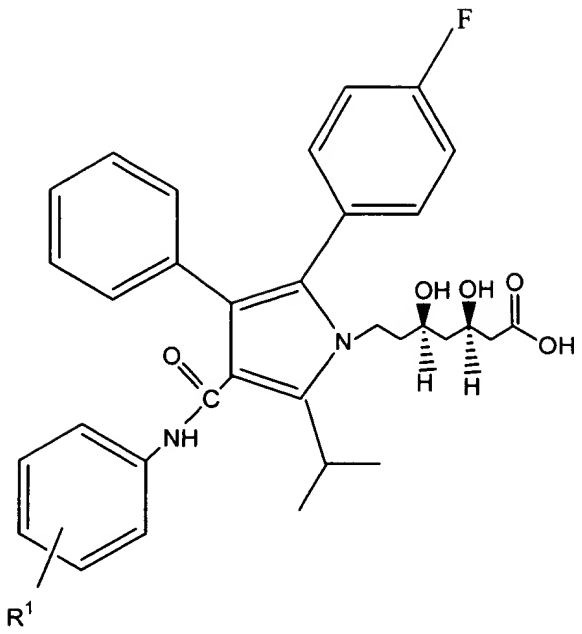
A2



Formula IA

wherein R^1 is hydroxy or the pharmaceutically acceptable salts thereof; and wherein said first compound and said second compound are each optionally and independently administered together with a pharmaceutically acceptable carrier, vehicle or diluent.

Please Cancel Claims 6 and 7.

Please Cancel Claims 15-20.

REMARKS

Applicants respectfully request reconsideration of the Office Office Action mailed on January 16, 2002 and allowance of the claims.

Applicants also wish to thank the Examiner for acknowledging the receipt of the Information Disclosure Statement submitted August 14, 2001. It is requested that the references listed on that previously submitted form PTO-FB-A820 be included in the "References Cited" portion of any patent issuing on this application (M.P.E.P. 1302.12).

Attached hereto is a "VERSION WITH MARKINGS TO SHOW CHANGES MADE". Additions are made by underline and deletions are made by strike-thru.

The rejection states that claims 5-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment or

prevention of the specific disease/disorders as specified at page 7, line 23 - page 8, line 9 of the present specification, does not reasonably provide enablement for a method of treatment in general wherein no specific therapeutic objection is provided. The rejection states that such reads on a panacea and the art currently is unaware of any single agent, or combination of agents that could be used for the treatment of any and all disease states. The rejection states that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicants traverse the 35 U.S.C. §112 rejection of the claims and respectfully request that the Examiner withdraw the rejection and allow the claims (as amended).

Applicants have amended claim 5 to recite the specific disease/disorders present in the dependent claims 9-14.

Claims, 1, 2, 5, 6, 9-16, 19 and 20 are rejected under 35 U.S.C. 102(a) as being anticipated by Deninno et al. (WO 00/17164) who teach methods for treating atherosclerosis, dyslipidemia, hypertriglyceridemis, hypercholesterolemis, cardiovascular disorders, angina (page 22, lines 25-28) through the administration of a composition which may comprise [2R,4S]-4-[(3,5-bis-trifluoromethyl-benzyl)-methoxycarbonyl-amino]-2-ethyl-6-trifluoromethyl-3,4-dihydro-2H-quinoline-1-carboxylic acid ethyl ester (page 9, lines 25-26) and a second compound which may be the HMG-CoA reductase inhibitor atorvastatin (page 29, line 26 and page 30, line 2) and kits containing such compositions (page 30, lines 18-28).

The rejection states that Applicant should note that present claims 19 and 20 are being interpreted as claims directed to a single composition because the statement of intended use, i.e., for use with a second pharmaceutical composition, does not impart any further physical or otherwise material limitation to the claimed composition.

Applicants have herein canceled claims 15-20.

Applicants traverse the 35 U.S.C. §102(a) rejection of the claims over Deninno et al. and respectfully request that the Examiner withdraw the rejection and allow the claims (as amended).

The Court of Appeals for the Federal Circuit, in ruling on the standard for anticipation under 35 U.S.C. §102(b), stated

> [i]t is elementary that an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice or device.

In re Donohue, 226 U.S.P.Q. 619, 621 (1985); and "...exclusion of a claimed element from a prior art reference is enough to negate anticipation by that reference." Atlas Power Co. v. E. I. duPont DeNemours & Co., 224 U.S.P.Q. 409, 411 (1984).

Applicants have deleted hydrogen as an R^1 substituent, thus deleting atorvastatin from the claims. Accordingly, Applicants submit that the claims are not anticipated by Deninno et al.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deninno, et al. (as above) in view of Roth (U.S. Patent No. 4,681,893).

The rejection states that the difference between the above and applicant's claimed subject matter lies in that Deninno, et al. teach only the compound atorvastation and not the presently claimed salts and/or hydroxy acid forms thereof.

The rejection also states that to the skilled artisan, applicant's claimed subject matter would have been obvious because Roth teaches the presently claimed salt forms and hydroxy acid forms of atorvastatin (see the abstract, column 2, line 3-43 and column 7, line 1-17) as being effective HMG-CoA reductase inhibitors and the skilled artisan would have been motivated to alternatively use the compounds of Roth for the same purpose as the atorvastatin of Dennino et al. because Dennino et al teaches atorvastatin for its HMG-CoA reductase inhibitory activity and Roth identified his compounds as being HMG-CoA reductase inhibitors.

Applicants traverse the 35 U.S.C. §103 rejection of the claims and respectfully request that the Examiner withdraw the rejection and allow the claims (as amended). Applicants submit that the combination of hydroxy substituted atorvastatin and [2R, 4S]4-[(3,5-bis-trifluoromethyl-benzyl)-methoxycarbonyl-amino]-2-ethyl-6-trifluoromethyl-3,4-dihydro-2H-quinoline-1-carboxylic acid ethyl ester is unobvious. Deninno et al. does not teach hydroxy substituted atorvastatin and there is no disclosure in Roth of the benefits of a combination of the hydroxy substituted atorvastatin with [2R, 4S]4-[(3,5-bis-trifluoromethyl-benzyl)-methoxycarbonyl-amino]-2-ethyl-6-trifluoromethyl-3,4-dihydro-2H-quinoline-1-carboxylic acid ethyl ester.

The points and concerns raised by the Examiner having been fully addressed. Applicants urge that this application is in condition for allowance, which action is respectfully requested.

Please charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 16-1445. Two copies of this sheet are enclosed.

Respectfully submitted,

Date: 7/12/2002

A. Dean Olson
Reg. No. 31,185
Attorney for Applicant

Pfizer Inc.
Patent Department MS8260-1611
Eastern Point Road
Groton, CT 06340
Tel.: (860)441-4904

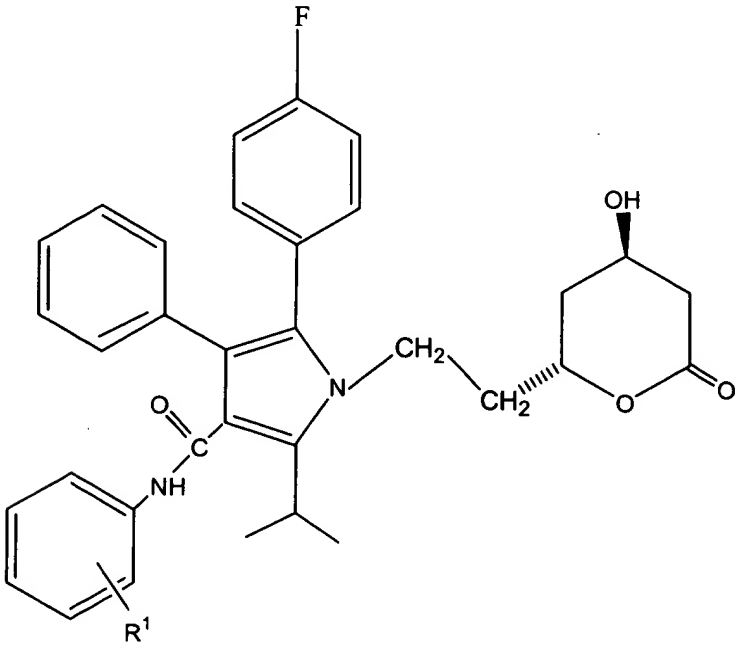
VERSION WITH MARKINGS TO SHOW CHANGES

Please amend Claim 1 as follows:

1. (Amended) A pharmaceutical composition comprising a therapeutically effective amount of a composition comprising:

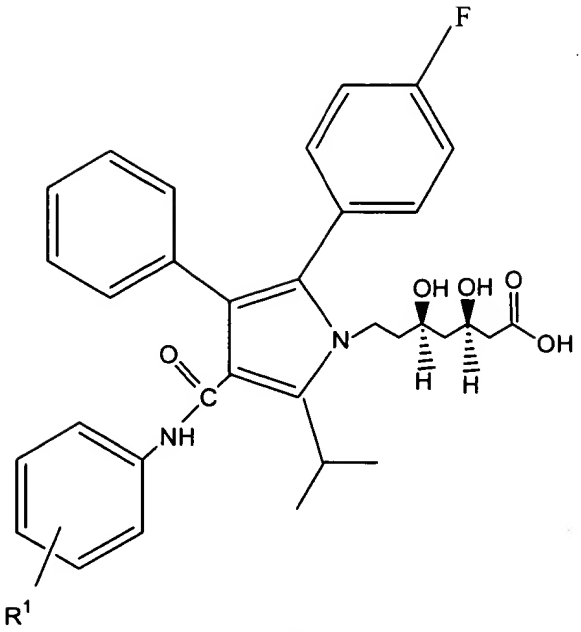
a. [2R, 4S]4-[(3,5-bis-trifluoromethyl-benzyl)-methoxycarbonyl-amino]-2-ethyl-6-trifluoromethyl-3,4-dihydro-2H-quinoline-1-carboxylic acid ethyl ester;

b. a compound of the Formula I



Formula I

or, the open chain Formula IA



Formula IA

wherein R^1 is ~~hydrogen or~~ hydroxy or the pharmaceutically acceptable salts thereof; and

c. a pharmaceutically acceptable carrier, vehicle or diluent.

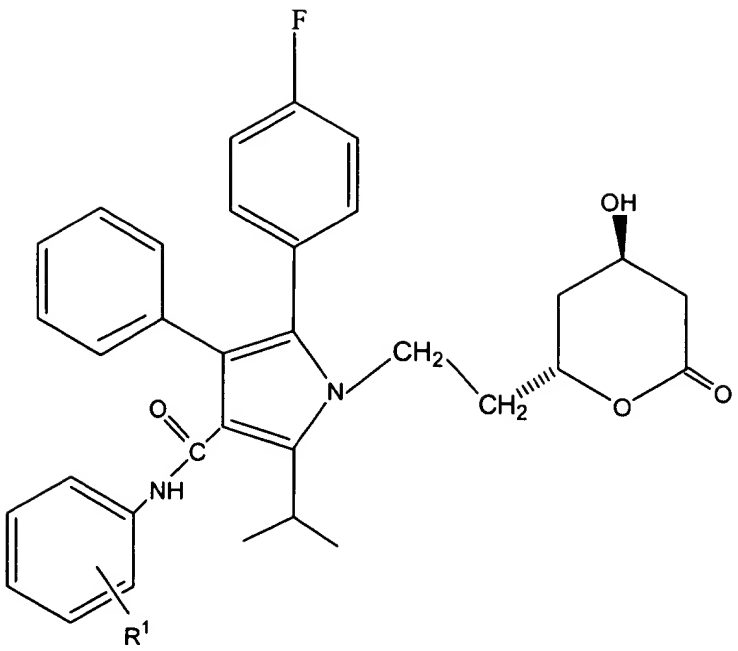
Please Cancel Claims 2-3.

Please amend claim 5 as follows:

5. (Amended) A method for slowing the progression of atherosclerotic plaques, causing the regression of atherosclerotic plaques or managing cardiac risk, or treating atherosclerosis, hyperlipidemia, HDL elevation or angina ~~treating~~ in a mammal in need of therapeutic treatment comprising administering to said mammal a therapeutically effective amount of:

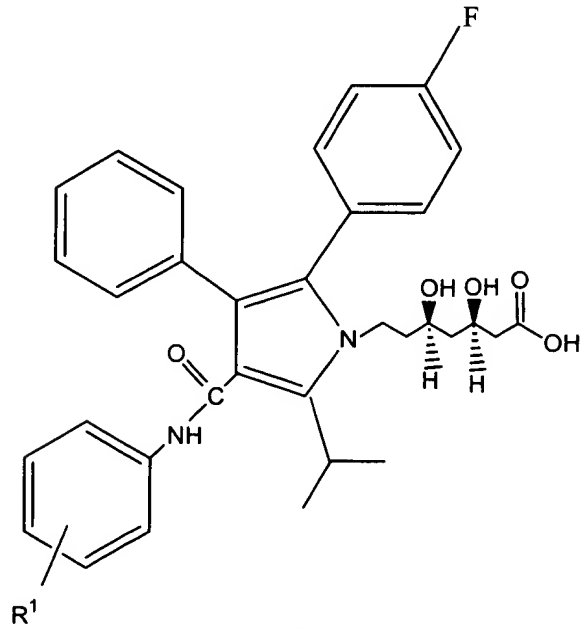
a a first compound, said first compound being [2R, 4S]4-[(3,5-bis-trifluoromethyl-benzyl)-methoxycarbonyl-amino]-2-ethyl-6-trifluoromethyl-3,4-dihydro-2H-quinoline-1-carboxylic acid ethyl ester; and

b. a second compound, said second compound being a compound having the Formula I



Formula I

or, the open chain Formula IA



Formula IA

wherein R^1 is ~~hydrogen or~~ hydroxy or the pharmaceutically acceptable salts thereof ; and

wherein said first compound and said second compound are each optionally and independently administered together with a pharmaceutically acceptable carrier, vehicle or diluent.

Please Cancel Claims 6 and 7.

Please Cancel Claims 15-20.